AMENDMENTS TO THE CLAIMS

Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A pharmaceutical aerosol formulation for use in a metered dose inhaler (MDI) consisting essentially of formoterol fumarate di-hydrate in suspension, a propellant and ethanol, wherein the formoterol fumarate di-hydrate has a water content of 4.8 to 4.28% by weight, and a steroid in solution.

2. (Cancelled)

3. (Previously Presented) The pharmaceutical aerosol suspension formulation according to claim 1, wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of formoterol fumarate di-hydrate that has a variance of no more than +/- 25%, of the mean Delivered dose when the formulation is stored at 40°C and 75% relative humidity for up to 6 months.

4. (Previously Presented) The pharmaceutical aerosol suspension formulation according to claim 1, wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of formoterol fumarate di-hydrate with a fine particle fraction of 30 to 70%.

5. (Previously Presented) The pharmaceutical aerosol suspension formulation according to claim 1, wherein the formoterol fumarate di-hydrate is provided as particles having a water content of about 4.8 to 4.28% by weight suspended in the propellant and solvent, and wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of the steroid that has a variance of no more than +/- 25%, of the mean Delivered dose when the formulation is stored at 40°C and 75% relative humidity for up to 6 months.

6. (Previously Presented) The pharmaceutical aerosol suspension formulation according to claim 5, wherein the formulation is capable of being dispensed from an MDI to provide a Delivered dose of steroid containing a fine particle fraction of 30% to 70%.

7. (Previously Presented) The formulation according to claim 1, wherein the steroid is selected from the group consisting of budesonide, ciclesonide, mometasone, fluticasone, beclomethasone, flunisolide, loteprednol, triamcinolone, amiloride, rofleponide or a pharmaceutically acceptable salt or derivative of these active compounds, selected from mometasone furoate, fluticasone dipropionate, beclomethasone dipropionate, triamcinolone acetonide and flunisolide acetate.

8. (Previously Presented) The formulation according to claim 7 wherein the steroid is ciclesonide.

9. (Previously Presented) The formulation according to claim 8 wherein the ciclesonide is present in an amount of 0.05 to 2 % by weight of the formulation.

10. (Previously Presented) The formulation according to claim 1, wherein the formoterol fumarate di-hydrate is present in an amount of 0.001 to 0.1% by weight of the formulation.

11. (Previously Presented) The formulation according to according to claim 1 containing a cromone selected from the group consisting of a pharmaceutically acceptable salt of cromoglycinic acid, nedocromil, and mixtures thereof.

12. (Previously Presented) The formulation according to claim 11 wherein the cromone is present in the formulation in an amount of 0.001 to 1%.

13. (Previously Presented) The formulation according to claim 1, wherein the propellant is selected from the group consisting of fluorochlorocarbons, alkanes, fluorinated alkanes, and hydrofluoroalkanes.

14. (Previously Presented) The formulation according to claim 13 wherein the propellant is a hydrofluoroalkane of the general formula:
$C_xH_yF_z$ (I);
in which x is the number 1, 2 or 3, y and z are each an integer greater than or equal to ($\geq$) 1, and $y+z=2x+2$.

15. (Previously Presented) The formulation according to claim 32 wherein the propellant is HFA 134a or HFA 227 or a mixture thereof.

16. (Previously Presented) The formulation according to claim 1, wherein the propellant is employed in an amount of greater than 90% by weight.

17. (Previously Presented) The formulation according to claim 1, wherein the ethanol is present in amounts of 1% to 8% by weight.

18. (Previously Presented) The formulation according to claim 1 comprising a surfactant selected from the group consisting of oleic acid, lecithin, sorbitan trioleate, cetylpyridinium chloride, benzalkonium chloride, polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, polyoxypropylene/polyoxyethylene block copolymers, polyoxypropylene/polyoxyethylene/ethylenediamine block copolymers, and ethoxylated castor oil.

19. (Previously Presented) The formulation according to claim 18 wherein the surfactant is present in an amount of 0.0001 to 1% by weight.

20. (Cancelled)

21. (Currently Amended) A vial containing the formulation according to claim 1 ~~or claim 20~~.

22. (Previously Presented) The vial according to claim 21 in the form of an aluminum, uncoated container.

23. (Previously Presented) The vial according to claim 21 adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of formoterol fumarate di-hydrate of about 3 to 15 micrograms.

24. (Previously Presented) The vial according to claim 21 adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of a steroid of about 10 to 1000 micrograms per puff.

25. (Previously Presented) The vial according to claim 24 adapted to be placed in a metered dose inhaler, and capable of delivering a dosage of fluticasone proprionate of about 50 to 500 micrograms per puff.

26. (Previously Presented) A package comprising the vial according to claim 21 comprising a label containing a dosage claim, wherein the mean Delivered dose of the active substances is no more than +/- 15% of the dosage stated on the label.

27. (Previously Presented) A metered dose inhaler containing the vial according to claim 21.

28. (Previously Presented) A method of producing a pharmaceutical aerosol formulation according to claim 1, comprising drying the formoterol fumarate di-hydrate to a water content of 4.8 to 4.28%.

29. (Previously Presented) The formulation according to claim 13, wherein the propellant is a fluorochlorocarbon selected from the group consisting of trichloro-monofluoromethane (F11), dichlorodifluoromethane (F12), monochlorotrifluoromethane (F13), dichloro-monofluoromethane (F21), monochlorodifluoromethane (F22), monochloromonofluoromethane (F31), 1,1,2-trichloro-1,2,2-trifluoroethane (F113), 1,2-dichloro-1,1,2,2-tetrafluoroethane (F114), 1-chloro-1,1,2,2,2-pentafluoroethane (F115), 2,2-dichloro-1,1,1-trifluoroethane (F123), 1,2-dichloro-1,1,2-trifluoroethane (F123a), 2-chloro-1,1,1,2-tetrafluoroethane (F124), 2-chloro-1,1,2,2-tetrafluoroethane (F124a), 1,2-dichloro-1,1-difluoroethane (F132b), 1-chloro-1,2,2-trifluoroethane (F133), 2-chloro-1,1,1-trifluoroethane (F133a), 1,1-dichloro-1-fluoroethane (F141b) and 1-chloro-1,1-difluoroethane (F142b).

30. (Previously Presented) The formulation according to claim 13, wherein the propellant is an alkane selected from the group consisting of propane, butane and isobutene.

31. (Previously Presented) The formulation according to claim 13, wherein the propellant is octafluoropropane (F218).

32. (Previously Presented) The formulation according to claim 13, wherein the propellant is a hydrofluoroalkanes selected from the group consisting of difluoromethane (HFA 32), pentafluoroethane (HFA 125), 1,1,2,2-tetrafluoroethane (HFA 134), 1,1,1,2-tetrafluoroethane (HFA 134a), 1,1,2-trifluoroethane (HFA 143), 1,1,1-trifluoroethane (HFA 143a), difluoroethane (HFA 152a) and 1,1,1,2,3,3,3-heptafluoropropane (HFA 227).

33. (Previously Presented) A metered dose inhaler containing the vial according to claim 22.